

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
11 April 2002 (11.04.2002)

PCT

(10) International Publication Number
WO 02/28268 A2

(51) International Patent Classification⁷: **A61B**

(21) International Application Number: PCT/US01/31160

(22) International Filing Date: 4 October 2001 (04.10.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/238,723 6 October 2000 (06.10.2000) US

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(81) Designated States (national): CA, JP, US.

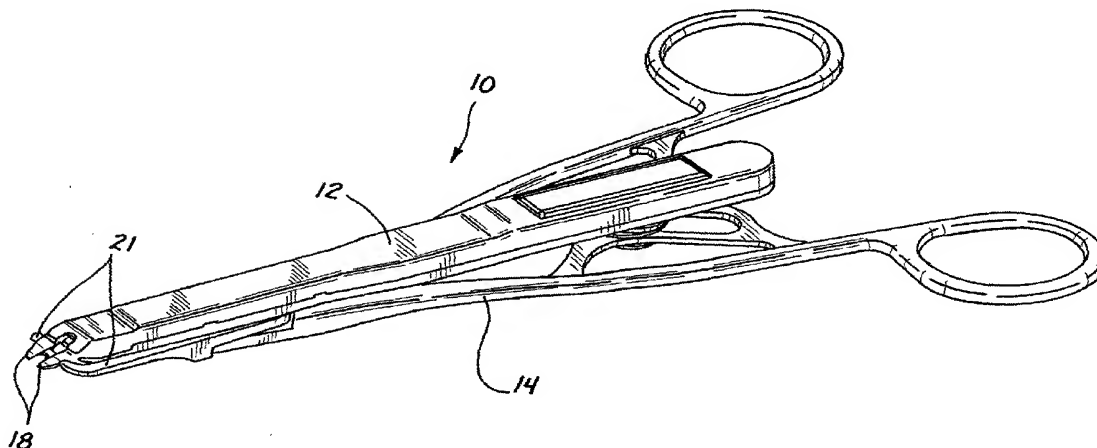
(84) Designated States (regional): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MULTIPLE CLIP APPLIER APPARATUS AND METHOD



(57) **Abstract:** A surgical clip applier includes a train of clips disposed in a plane with a single clip removed from the train of clips and disposed in a staging position. A pair of jaws are adapted to receive the single clip from the staging position by operation of a jawloader moveable outside the plane of the train of clips. In an associate method, a handle assembly is provided which is moveable in an open stroke and a closed stroke. A source of surgical clips are provided along with a pair of jaws which are adapted to receive one of the clips as the handle assembly is moved in an open stroke, the jaws are open to receive the clip. Following the opening of the jaws, a jaw loader is extended to a position between the jaws to move the clip into the jaws. The handle assembly is moveable in a closed stroke during which the jaws are closed to crimp the clip. Prior to this closing of the jaws, the jaw loader is retracted from the position between the jaws leaving the clip in the jaws.



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MULTIPLE CLIP APPLIER APPARATUS AND METHOD

Cross Reference to Related Applications

5 This is a non-provisional application incorporating by reference the disclosures in
provisional application, Serial No. 60/238,723, filed on October 6, 2000, and entitled Multiple
Clip Applier Apparatus and Method; co-pending PCT application No. PCT/US00/01296 filed on
January 19, 2000 and entitled "Modular Ligating Apparatus and Method", and also US Patent
Application No. 60/117,079 filed on January 25, 1999 and entitled : "Modular Ligating Apparatus
10 and Method."

Background of the Invention

Clip appliers of the past have included cartridges containing multiple clips.
These cartridges have been automatically actuated and accordingly have not offered the tactical
feedback desired by surgeons. In addition, automatic clip appliers have been exceedingly
15 complex typically requiring not less than 22 moving parts. Tactical feedback is appreciated as it
gives a surgeon some indication as to the amount of force being applied by the clip to the body
tissue, such as a blood vessel. Only single clip appliers have provided this tactical feedback.

Multiple clip appliers have used jaw loaders to individually load each clip into the
jaws of the applier. Removing the jaw loaders from between the jaws prior to crimping the clip
20 has sometimes resulted in jamming.

Summary of the Invention

In accordance with the present invention, a multiple clip applier is disclosed which provides a high degree of tactical feedback with only six moving parts. The resulting applier provides the desired feedback with a relatively simple mechanisms and a high degree of reliability.

A mechanical delay circuit is disclosed which loads a clip only in the last five (5) percent of the opening stroke and removes the clip loader in the first five (5) percent of the closing stroke. These steps of loading and removing are accomplished in a positive, substantially instantaneous manner. The resulting efficiency, reliability, disposability, alignment, tactical feedback, and repeatable operation can all be appreciated within the scope of this invention.

These and other features and advantages of the invention will be better understood with a description of preferred embodiments and reference to the associated drawings.

Description of the Drawings

Fig. 1 is a top-side perspective view of one embodiment of the clip applier of the present invention;

Fig. 2 is a bottom side perspective view of the clip applier illustrated in Fig. 1;

Fig. 3 is an exploded view of the clip applier showing a disposable clip cartridge removed from a snap-fit relationship with a handle assembly;

Fig. 4 is an exploded view of one embodiment of the cartridge associated with the present invention;

Fig. 5a is a top-side perspective view of a clip train and clip advancer mechanism;

Fig 5b is a time line showing the sequence of operation in a preferred embodiment of the invention;

Fig. 6 is a top-side perspective view of a slide block retractor and jaw loader mechanism relatively positioned at the beginning of a retraction stage;

5 Fig. 7 is a top-side perspective view of the retractor slide block and jaw loader showing the jaw loader in a retracted position;

Fig. 8 is a top-side perspective view of the retractor slide block and jaw loader, each in its retracted position;

10 Fig. 9 is a top-side perspective view showing the retractor, slide block and jaw loader at a late stage in the closing strokes;

Fig. 10 is an axial cross section view of the slide block and jaw loader at the stage illustrated in Fig. 9;

Fig. 11 is an axial cross section view similar to Fig. 10 and showing the slide block releasing a keeper to initiate advancement of the jaw loader;

15 Fig. 12 is a top-side perspective view showing the slide block and jaw loader at a late stage in the opening stroke; and

Fig. 13 is a top/slide perspective view showing the slide block and jaw loader at an ultimate stage of the opening stroke;

20 Fig. 14 is a perspective view of a clip loading arrangement including a clip staging position; and

Fig. 15 is a perspective view of a further embodiment of a clip loading arrangement.

Description of Preferred Embodiments

A multiple-clip clip applier of the present invention is illustrated in Figure 1 and designated by the reference numeral 10. The clip applier 10 includes a disposable cartridge 12, and a non-disposable handle assembly 14 which can be coupled to the cartridge 12 in a snap-fit relationship as illustrated in Figure 1. At a distal end 16 of the applier 10, the cartridge 12 is provided with metal jaws 18 which are disposable with the cartridge 12. The jaws 18 are biased to an open state but moveable to a closed state. The handle assembly 14 has a scissors configuration and a pair of pawls 21 at the distal end 16 which can be moved together to close the jaws 18, and can be moved apart to permit the jaws 18 to open. The self alignment of the jaws 18 is of particular advantage to the present invention and generally guaranteed with the replacement of each disposable cartridge 12. This self alignment of the jaws 18 is disclosed in greater detail in PCT Application Serial No. PCT/US00/01216. This alignment of the jaws 18 is independent of the alignment or misalignment of the pawls 21 as disclosed in greater detail in U.S. Patent Application Serial No. 60/117079. This latter application also discloses operation of the handle assembly 14 which includes a pair of converging slots 23 and 25, best illustrated in the bottom view of Figure 2. The handle assembly 14 is operable like a pair of scissors with an opening stroke and a closing stroke. A button 27 rides within the converging slots 23, 25 between a distal position associated with the end of the opening stroke and a proximal position associated with the end of the closing stroke.

The cartridge 12 in this embodiment is snap-fit to the handle assembly 14 at a fulcrum 29 and also through a cartridge drive pin 30 at the button 27. This snap-fit relationship is best illustrated in the assembly view of Figure.

Figure 4 shows an exploded view of the cartridge 12 which in this case includes a
5 bottom housing 32, a top housing 34 with a platform 35, and a housing cap 36. The bottom housing 32 includes a clip train channel 38 and a pair of upstanding walls 41 terminating proximally in a ball housing 43 and a wall 45. The bottom housing also includes a keeper 47, having a pair of ramped actuators 50. A pair of inclined elements 52 are also provided along with distal walls 54 and a drive pin slot 56.

10 The cartridge 12 is initially assembled by placing a plurality of clips 57 into the channel 38. In this embodiment, the clips 57 are aligned end-to-end to form a clip train 59. The clip train 59 is biased in the distal direction by a clip advancer 61 which rides within the channel 38. The advancer 61 moves along a rod 63 and is biased distally by a spring 65. At the proximal end of the rod 63, a ball or enlargement 67 is formed and seated in a fixed relationship with the
15 ball housing 43.

A retractor 70 moves along the bottom housing 32 and includes an upstanding tab 72, a pair of abutments 74, an inclined tab 76, a drive pin slot 78, and a tongue 81 extending from a pair of shoulders 83. A compression spring 85 is mounted on the tongue 81 and is compressed between the shoulders 83 and the upstanding walls 54.

5 A slide block 90 is disposed over the retractor 70 and includes a pair of upstanding walls which define a longitudinal slot configured to receive the inclined tab 76. A drive pin 94 is seated in the block 90 and extends through the slot 78 in the retractor 70, as well as the slot 56 in the bottom housing 32.

A jaw loader 101 is of particular interest to the present invention. It
10 includes a distally extending tongue 103 terminating in a V-slot 105 which is complimentary in shape to the clips 57. Proximally of the tongue 103, a tunnel 107 is formed over a slot 109 which is shaped to receive the clip advancer rod 63. The tunnel 107 terminates at a proximal surface 111. Proximally of this surface 111, an axial slot 113 extends to a proximal wall 115 which includes a spring tab 117. Outwardly of the
15 slot 113, a pair of wings 121 and 123 are provided with a leaf spring configuration. In its assembled state, the tab 72 of the retractor 70 is disposed within the slot 113 distally of the wall 115. The jaw loader 101 is positioned distally of the slide block 90 with a tension spring 125 disposed between the walls 92 and attached at opposite ends to the spring tab 117 on the jaw loader 101 and the inclined tab 76 on the retractor 70.

20 The top 34 registers with the bottom 32 to form a housing of the cartridge 12. The top 34 also provides the platform 35 to receive the jaws 18 and their associated alignment assembly 126 and jaw spring 127. The cap 36 forms a cover over this platform 35.

Operation of the cartridge 12 involves two generally separate and
25 independent mechanisms: (1) a continuous and ongoing mechanism for advancing the
clip train 59, and (2) a delay mechanism for loading the next clip into the jaws.

The continuous and ongoing portion of this process is associated with the
clip advancer 61 as illustrated in Figure 5a. In this view, the train 59 of clips 57 is urged
distally by the clip advancer 61 which in turn is biased to move distally along the rod 63
30 by the spring 65. This bias of the clip train 59 continues generally independently of any
other function associated with the clip applier 10.

The remaining operation of the clip applier 10 is repetitive so one must
pick a point in the cycle to begin this discussion. For purposes of discussion, it will be
assumed that the process begins with a single clip 57 disposed in the jaws 18 at the
35 completion of the opening stroke when the handles of the assembly 14 (Figure 1) are
maximally separated. This point is designated by the reference numeral 126 along a
cycle time line 128 illustrated in Figure 5b.

At this point in time, the jaw loader 101 is disposed at its distal most position where it
extends between the jaws 18. The retraction spring 125 is fully extended or stretched
40 while the retractor spring 85 is generally uncompressed. With the handle assembly 14
maximally opened, the drive pin 94 associated with the slide block 90 is in its distal most
position.

In order to crimp the clip 57 and the jaws 18, the natural motion of the
handle assembly 14 is to move the handles together. Thus begins the closing stroke at
45 point 124 of the time line 126. As the handles of the assembly are brought into

proximity, the pawls 21 push against the bias of the jaw spring 127 to close the jaws 18 and thereby crimp the clip 57.

Before the clip 57 can be crimped however, the jaw loader 101 must be removed from between the jaws 18. This is accomplished with the delay mechanism previously discussed, which responds almost immediately to the proximal movement of the drive pin 94 as shown by a point 128 in Figure 5b. With reference to Figure 6, it will be noted that when the drive pin 94 moves proximally the slide block 90 is carried with it along with the retractor 70. The jaw loader 101 is also moved proximally due to its engagement with the tab 72 of the retractor 70.

As this proximal movement continues, the wings 121 and 123 of the jaw loader 101 ride up on the inclined elements 52 formed in the bottom 32 of the housing. As the wings 121 and 123 ride up on the inclined elements 52, the proximal wall 115 clears the abutments 74. This causes the jaw loader 101 to snap proximally until the surface 111 associated with the tunnel 107 contacts the upstanding walls 41 of the bottom 32. Thus, at an early stage in the closing stroke, the jaw loader 101, and particularly the tongue 103, is rapidly and positively withdrawn from between the jaws 18. The remainder of the closing stroke, beginning at a point 129 for example, moves the pawls 21 against jaw 18 thereby crimping the clip 57 to a point 130 in Figure 5b which represents the end of the close stroke and the beginning of the open stroke. Note that approximately 90 percent of the closing stroke is devoted to the tactile feedback associated with crimping the clip 57 onto the tissue. As the handle assembly 14 continues to be closed, the drive pin 94 is drawn proximally along with the retractor 70 thereby compressing the retractor spring 85. With the jaw loader 101 stopped by the

walls 41, the continued proximal movement of the slide block 90 and retractor 70

70 stretches the tension spring 125 to its maximum extent.

This completes the closing stroke of the process at the point 129, crimping the clip 57 onto the tissue. It is now desirable to open the jaws 18 in order to release the crimped clip, and to load a new clip 57 into the jaws 18.

In order to open the jaws 18, the normal movement of the handle assembly
75 is to separate the handles in an opening stroke which, for a preferred embodiment, begins at the point 130 along the time line 126. At the beginning of this stroke, when the handles of the assembly 14 are initially moved apart, the drive pin 94 begins its distal movement. Approximately 95 percent of this distal movement is associated with spreading the pawls 21 so that the jaws can separate under the bias of the spring 127. As
80 the handle assembly 14 continues to be open, the drive pin is moved distally carrying the slide block 90 into proximity with its distal most position. This point is designated by the reference numeral 131 in Figure 5b. No other forces act on the slide block 90 until it reaches the actuators 50 associated with the keeper 47.

As the handle assembly 14 is further opened and the slide block 90 is
85 driven further in the distal direction, the block 90 depresses the actuators 50 as well as the keeper 47. When the keeper 47 is sufficiently depressed, the retractor 70 snaps distally, causing the abutments 74 to push against the proximal wall 115, forcing the clip loader 101 to move the next clip 57 into the jaws 18. It will be noted that this movement of the next clip 57 is accomplished at the end of the open stroke in a positive and instantaneous
90 manner. This ensures that the jaws 18 are fully open and ready to receive the next clip 57 before it is moved into position. Only then does the retractor 70 respond to the

compression of the retractor spring 85 to move the jaw loader 101 against the clip. As the jaw loader 101 is snapped distally, the wings 121 and 123 are bent inwardly by the inclined elements 152 as illustrated in Figure 12 until the wings 121, 123 clear the
95 elements 152 as illustrated in Figure 13. This figure 13 is the same as Figure 6 reflecting that the process has been completed with a new clip 57 loaded in the jaws 18 and the clip loader 101 in its fully distal position. A point 133 on the time line 126 designates the end of the open stroke.

The points along the timeline 126 can be further defined for a preferred
100 embodiment of the clip applier 10. In this embodiment, it will be noted that the pawls 21 of the handle assembly 14 are increasingly separated in the open stroke until they reach a space relationship. The pawls 21 are increasingly moved together in the closed stroke until they reach a fully proximate position. As noted, the jaws 18 are biased to an open state but are moveable to a closed state. In this embodiment, when the pawls 21 are in
105 the fully spaced relationship, the jaws 18 are biased to their open state. However, in this embodiment, the pawls 21 are open further in their fully spaced relationship than the jaws 18 in their open position. As a result, the handle assembly disengages and is spaced from the pawls 21 at the end of the open stroke and the beginning of the closed stroke.

In operation, the point 124 on the timeline 126 is characterized in this
110 embodiment by the pawls 21 in the fully spaced relationship, the jaws 18 in the open state, and the jaw loader 101 in the distal position between the jaws 18. As the closed stroke begins, the point 128 is defined by the jaws 18 in the open position, the clip between the jaws in the open state and the jaw loader 101 retracted to the proximate

position. Although the pawls 21 may have begun movement toward the closed position,
115 they have not yet engaged the jaws 18 in this particular embodiment.

At the point 129 on the timeline 126, the pawls 21 first engaged the jaws
18. Note that this point 129 follows the point 128 when the jaw loader 101 was fully
retracted. Between the points 129 and 130, the pawls 21 move the jaws 18 against their
normal bias to their closed or fully proximate relationship. This of course, causes the clip
120 57 to be crimped. If it is desired that the clip 57 be left in a less than fully crimped state,
the jaw assembly 14 can be reversed between the points 129 and 130 to disengage the
clip 57 at its less than fully crimped state. With the clip applier 10 removed from the
operative site, the handle assembly 14 can close to the point 130 wherein the pawls 21 are
at their fully proximate relationship and the jaws 18 are in their closed position.

125 As the open stroke begins at the point 130, the pawls 21 begin to spread,
permitting the jaws 18 to separate under their own bias toward the open position.
Eventually, the jaws 18 reach their fully open position, for example, at the point 131.
Immediately following the point 131, the pawls 21 disengage the jaws 18. In the
remainder of the open stroke, the jaw loader 101 moves distally pushing before it the next
130 clip in the train 59.

Another aspect of the present invention is associated with operation of the
clips 57 in the train 59. As noted, a continuous distal pressure is asserted on the back of
the train 59 biasing the clips 57, by operation of the spring 65, in the distal direction.
This moves the distal most clip in the train 59 to a staging position where it is 1) elevated
135 above the plane of the clip train 59. This is illustrated in greatest detail in Figure 14
which shows a clip 130 loaded in the jaws 18, 2) a clip 132 disposed in the elevated

staging position above the train 59, and 3) a clip 134, the ultimate clip in the train 59.

When the clip 130 leaves the jaws 18, and the clip 132 advances into the jaws 18 and the clip 134 moves into the staging position. In the staging position, the clip 132 is held
140 by a detent 137 which is then elevated by the jaw loader 101 releasing the clip 132 and snapping the clip 132 into the jaws 18.

In a similar arrangement illustrated in Figure 15, the clip train 59 is formed by clips 57 which are disposed in respective parallel planes. In this arrangement the clip loader 101 operates directly on the ultimate clip 57 to move that clip directly
145 from the train 59 into the jaws 18. In this case, the clips 57 forming the train 59 can be joined by glue 138 as illustrated in Figure 15.

It will be understood that many other modifications can be made to the various disclosed embodiments without departing from the spirit and scope of the concept. For example, various sizes of the surgical device are contemplated as well as
150 various types of constructions and materials. It will also be apparent that many modifications can be made to the configuration of parts as well as their interaction. For these reasons, the above description should not be construed as limiting the invention, but should be interpreted as merely exemplary of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the present
155 invention as defined by the following claims.

CLAIMS

1. A surgical clip applier, comprising:
a train of clips disposed in a plane;
a single clip removed from the train of clips and disposed in a
staging position;
5 a pair of jaws sized and configured to receive this single clip from
the staging position; and
a jaw loader moveable outside the plane of the train of clips for
advancing the single clip from the staging position into the jaws.
2. The surgical clip applier recited in Claim C1, wherein:
the plain of the train of clips is a first plane; and
the single clip in the staging position is disposed in a second plane,
generally parallel to the first plane.

3. The surgical clip applier recited in Claim 1, further comprising:
a spring for biasing the train of clips generally toward the jaws;

and

- 5 the spring being adapted to move the train of clips independently
of the jaw loader.

4. The surgical clip applier recited in Claim 1, wherein:
the single clip and the jaw loader facilitate maintenance of the clips
of the clip train in the plane of the clip train.

5. A method for operating a surgical clip applier, comprising the steps of:

providing a handle assembly alternatively moveable in an open stroke and a close stroke;

5 providing a source of surgical clips;

providing a pair of jaws sized and configured to receive one of the surgical clips, moving the handle assembly in the open stroke;

during the moving step, opening the jaws to receive the clip;

during the moving step and following the opening step, extending

10 a jaw loader to a position between the jaws to move the clip into the jaws;

moving the handle assembly in the close stroke;

during the second moving step, closing the jaws to crimp the clip;

and

during the second moving step and prior to the closing step,

15 retracting the jaw loader from the position between the jaws, leaving the clip in the open state in the jaws.

6. The method recited in Claim 5, further comprising the steps of:

during the first moving step, providing the handle assembly with a pair of handles relatively moveable over a particular distance from a spaced relationship to a proximate relationship;

5 during the second moving step, moving the handles relative to each other over a portion of the particular distance to complete the retracting step; and

the portion of the particular distance being less than about one-tenth the particular distance.

7. The method recited in Claim 6, wherein:

the portion of the particular distance is less than about one-twentieth of the particular distance.

8. The method recited in Claim 5, further comprising the steps of:

during the extending step, holding the jaw loader in the position between the jaws with an abutment; and

during the retracting step, moving the jaw loader away from the
5 abutment to facilitate retraction of the jaw loader.

9. The method recited in Claim 7, further comprising the steps of:
prior to the holding step, sliding the jaw loader distally over the
abutment to engage the abutment; and
during the second moving step, raising the jaw loader over the
5 abutment to disengage the abutment.

10. The method recited in Claim 5, further comprising the steps of:
providing a handle assembly including a pair of handles relatively
moveable from a spaced relationship associated with a fully open relationship of the jaws,
and a proximal relationship associated with a fully closed relationship of the jaws;
5 moving the handles from the spaced relationship to the proximal
relationship; and following the retracting step and prior to reaching the fully closed state
of the jaws, reversing the handles towards the spaced relationship to remove the jaws
from the clip.

11. The method recited in Claim 7, further comprising the step of:
following the retracting step, recycling the clip loader to load
another clip into the jaws.

12. A method for operating a surgical clip applier, comprising the steps of:

providing a source of clips, each moveable from an open state to a closed state;

5 providing a pair of jaws sized and configured to receive one of the clips in the open state;

providing a handle assembly, including a pair of handles moveable over a particular distance from a proximate relationship to a spaced relationship;

10 extending a jaw loader to a position between the jaws to move the one clip into the jaws;

bending the clip from the open state to the closed state;

moving the handles a first relative distance toward the spaced relationship to disengage the closed clip;

15 moving the handles a second relative distance towards the spaced relationship to extend the jaw loader to the position between the jaws and to move another clip into the jaws; and

the first relative distance being greater than about ten times the second relative distance.

13. The method recited in Claim 12, wherein the first relative distance is greater than about twenty times the second relative distance.

14. A method for operating a surgical clip applier, comprising the steps of:

providing a source of surgical clips;

providing a handle assembly operable with an opening stroke and a

5 closing stroke;

providing a pair of jaws having an open position and a closed position;

providing a jaw loader with properties for moving a first one of the clips into the jaws;

10 during the opening stroke of the handle assembly, moving the jaw loader between the jaws to load the first clip into the jaws;

during the closing stroke of the handle assembly, removing the jaw loader from between the jaws, leaving the one clip in the jaws; and

15 engaging the jaws with the handle assembly during the closing stroke of the handle assembly to close the jaws and the first clip.

15. The method recited in Claim 14, wherein the engaging step follows the removing step.

16. The method recited in Claim 14, further comprising the steps of:
disengaging the handle assembly from the jaws and the first clip;
and
loading a second one of the clips into the jaws.

17. The method recited in Claim 16 wherein the loading step follows the disengaging step.

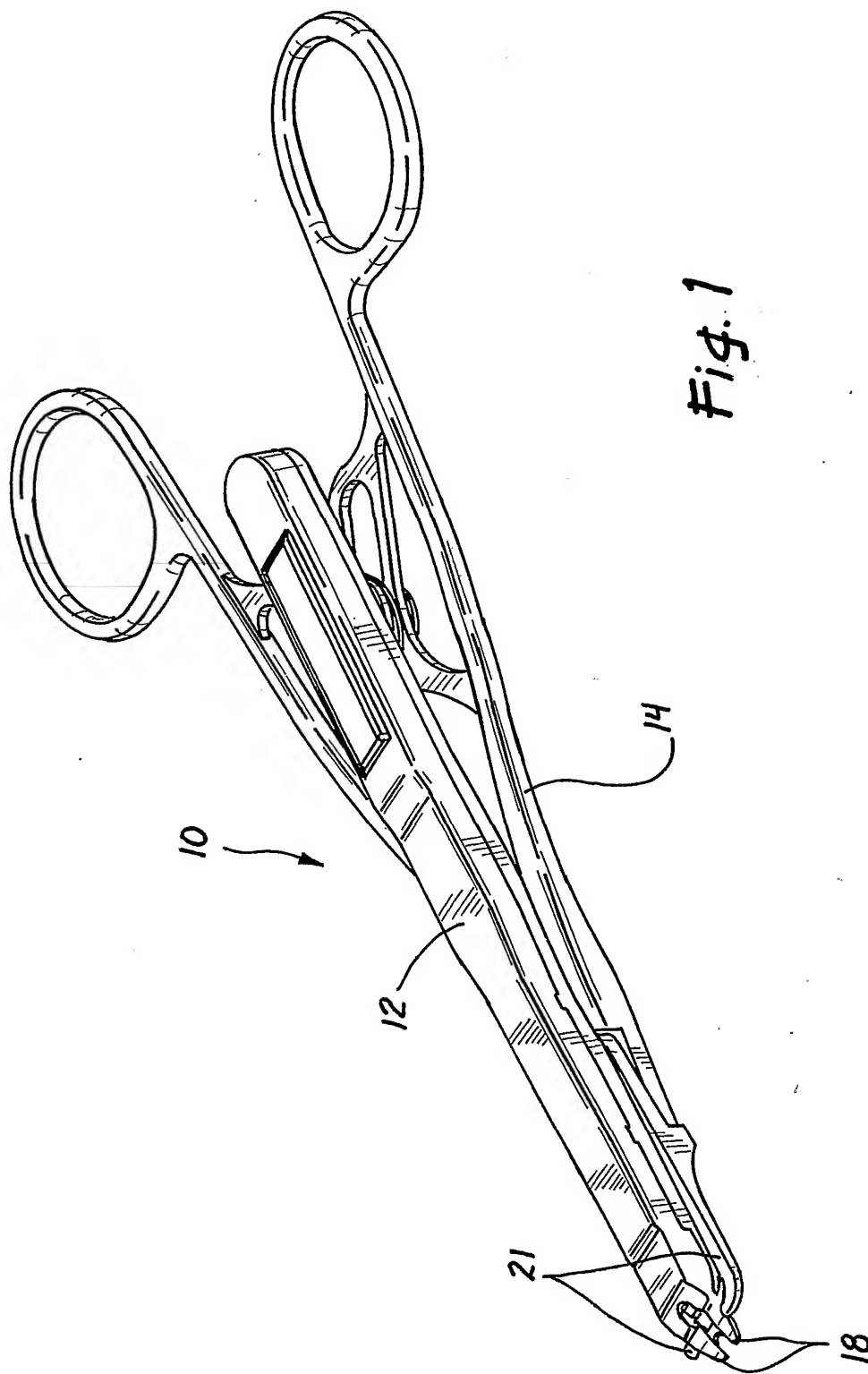
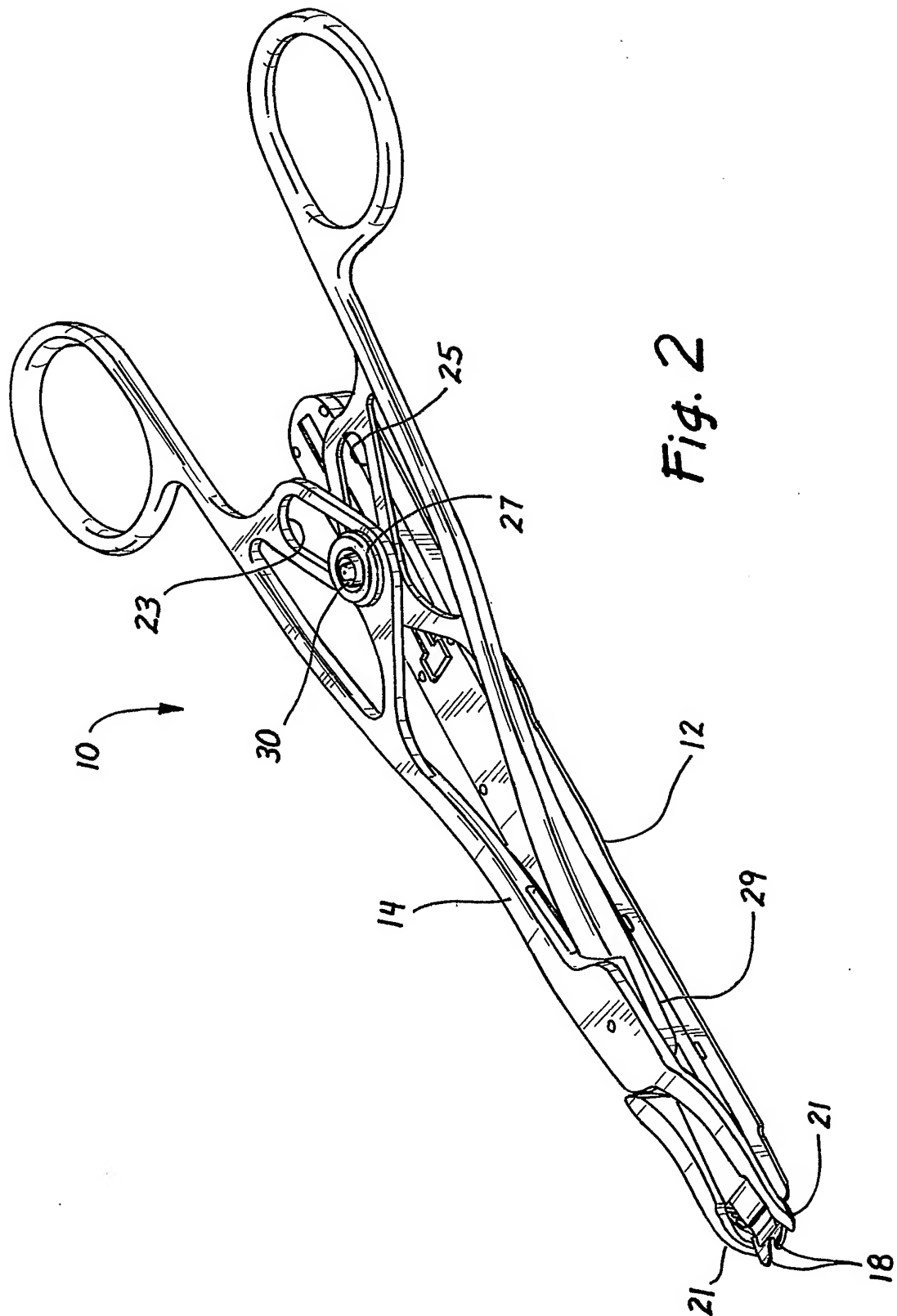
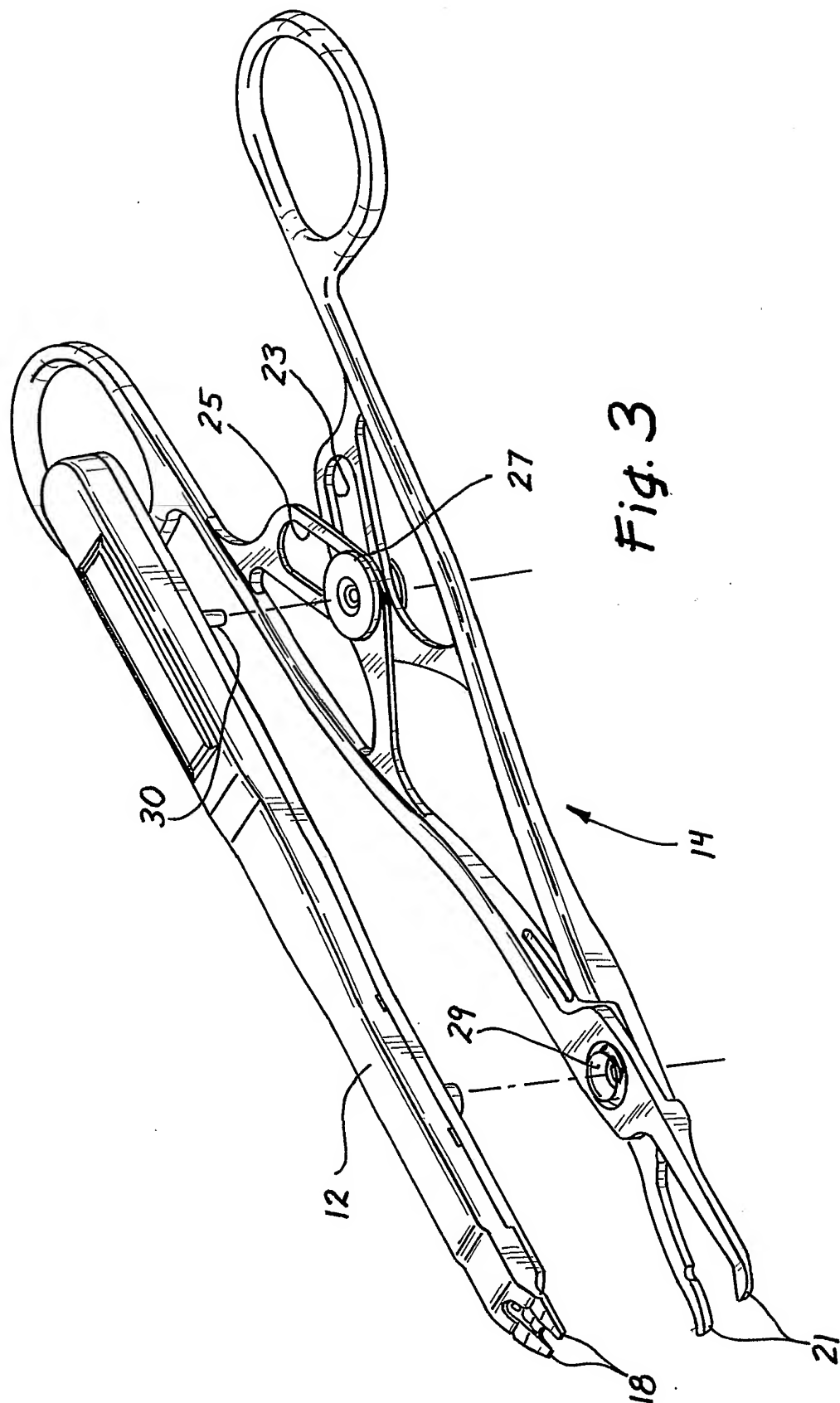


Fig. 1





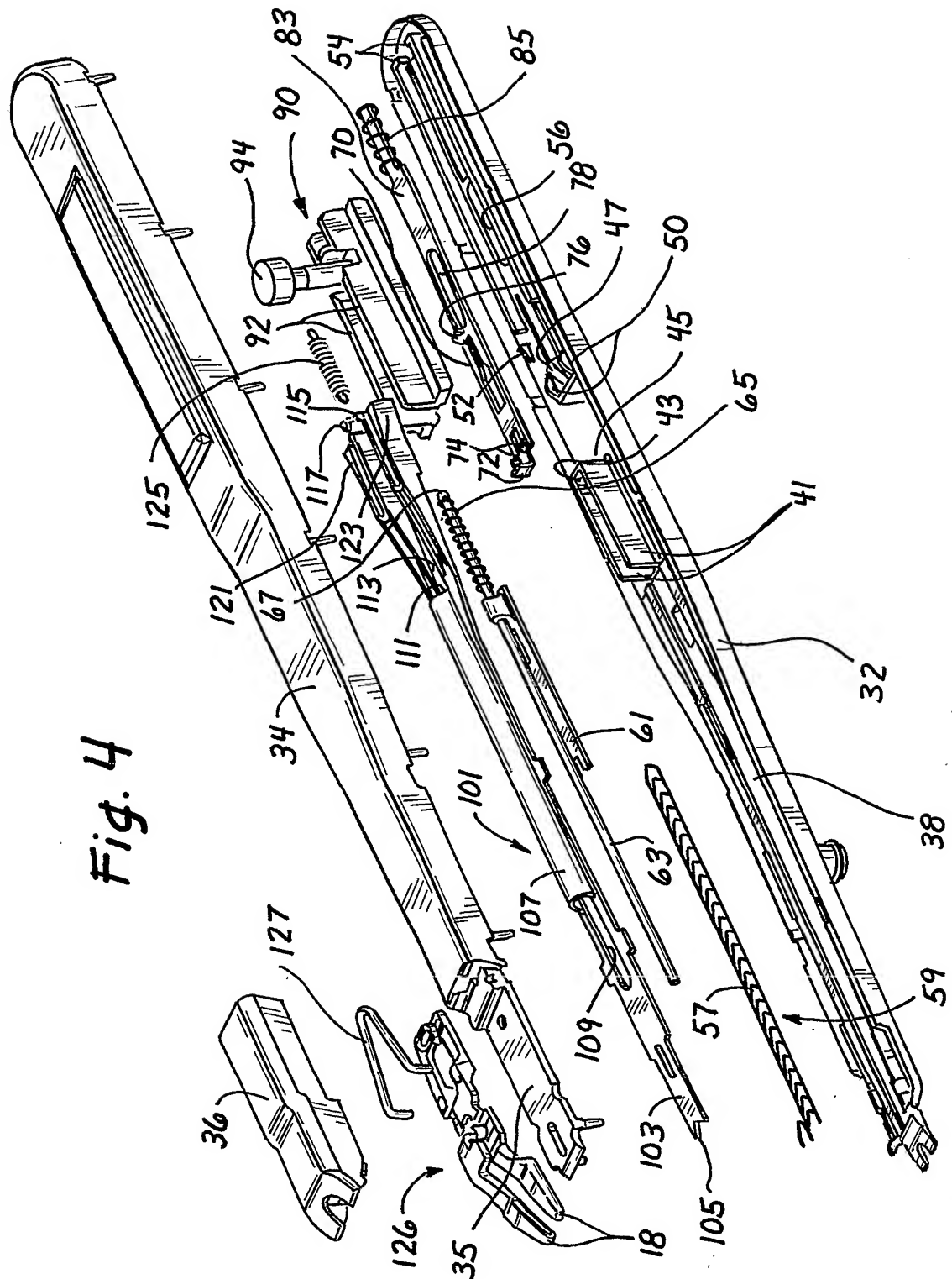


Fig. 4

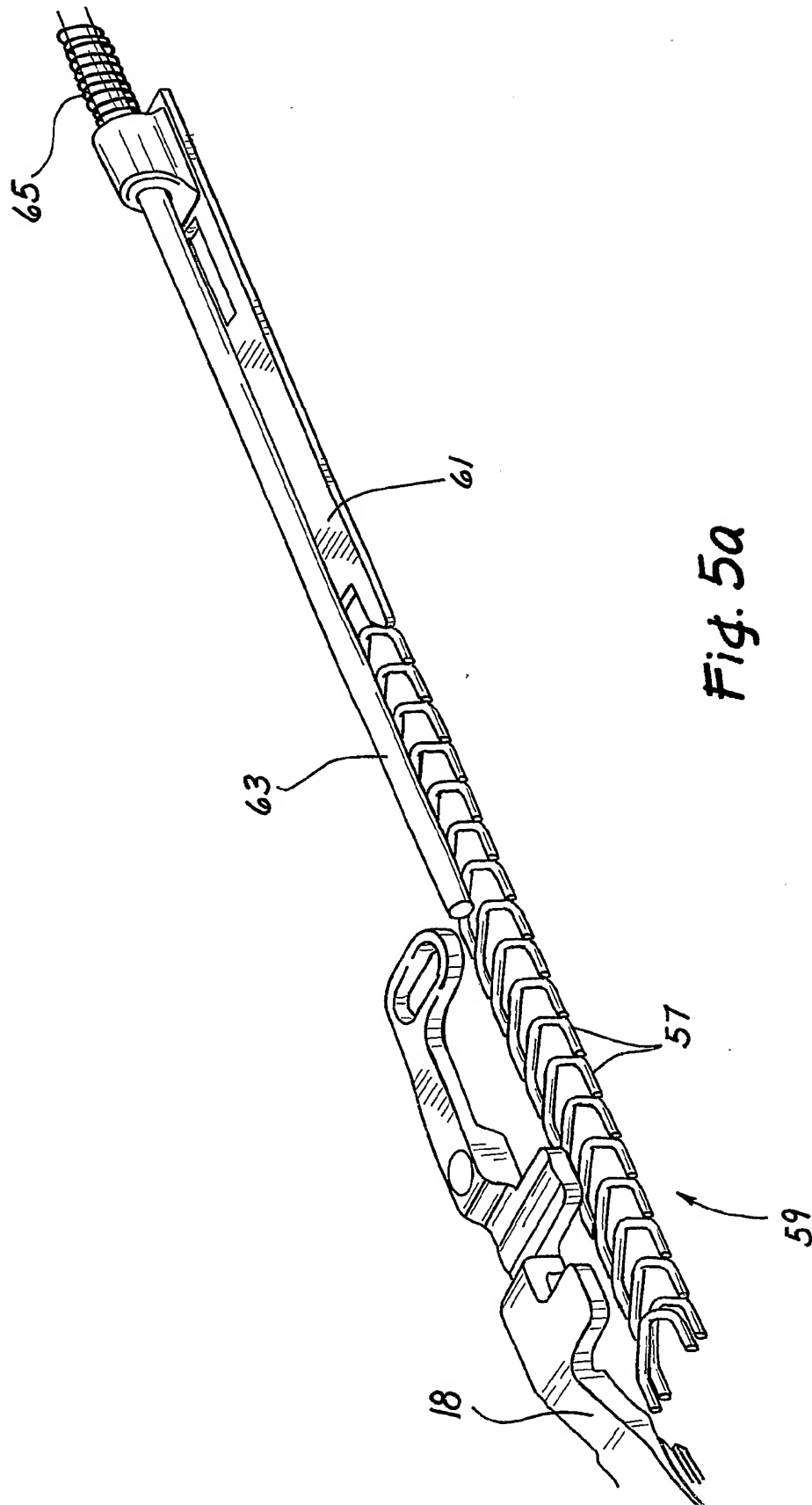
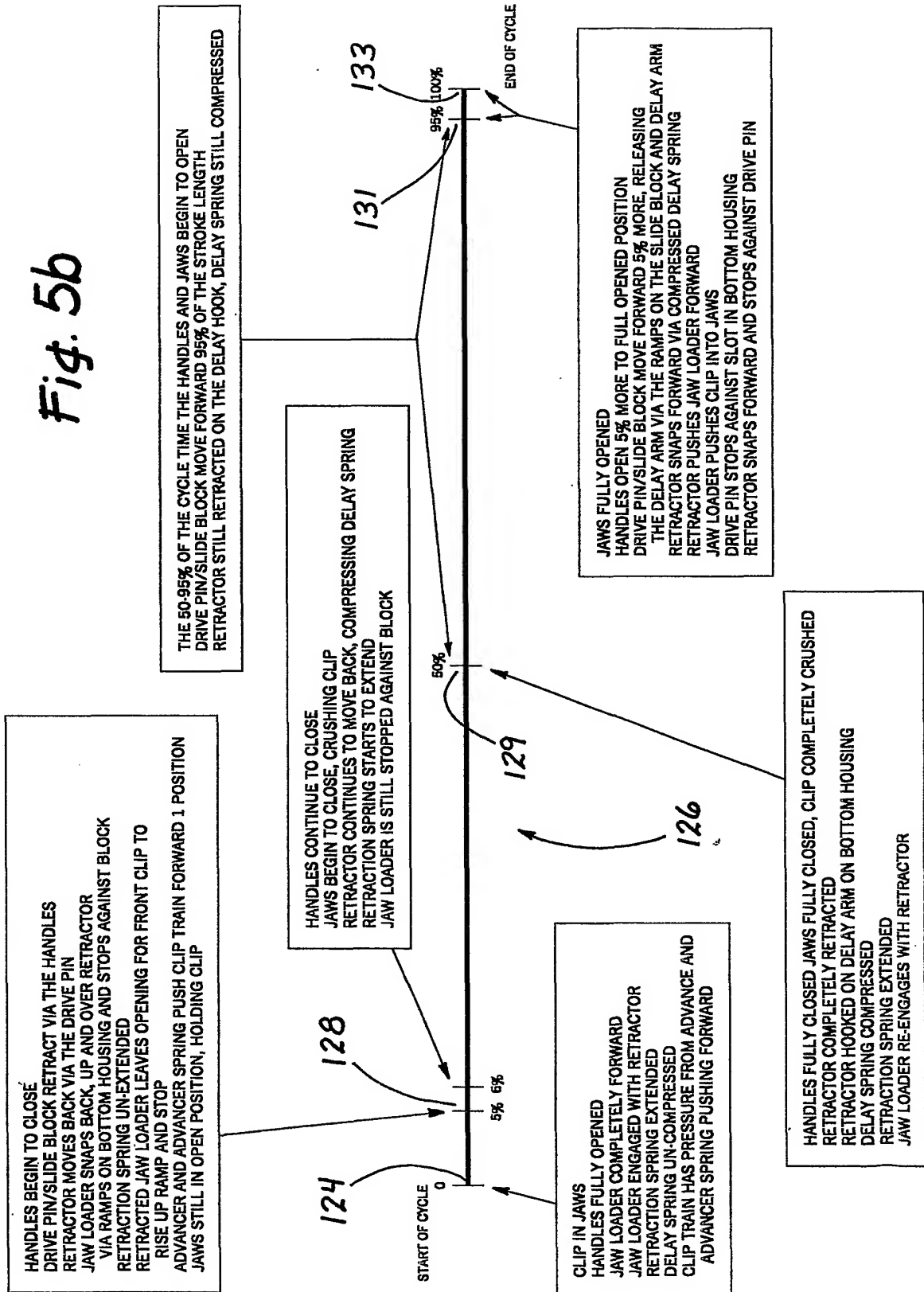
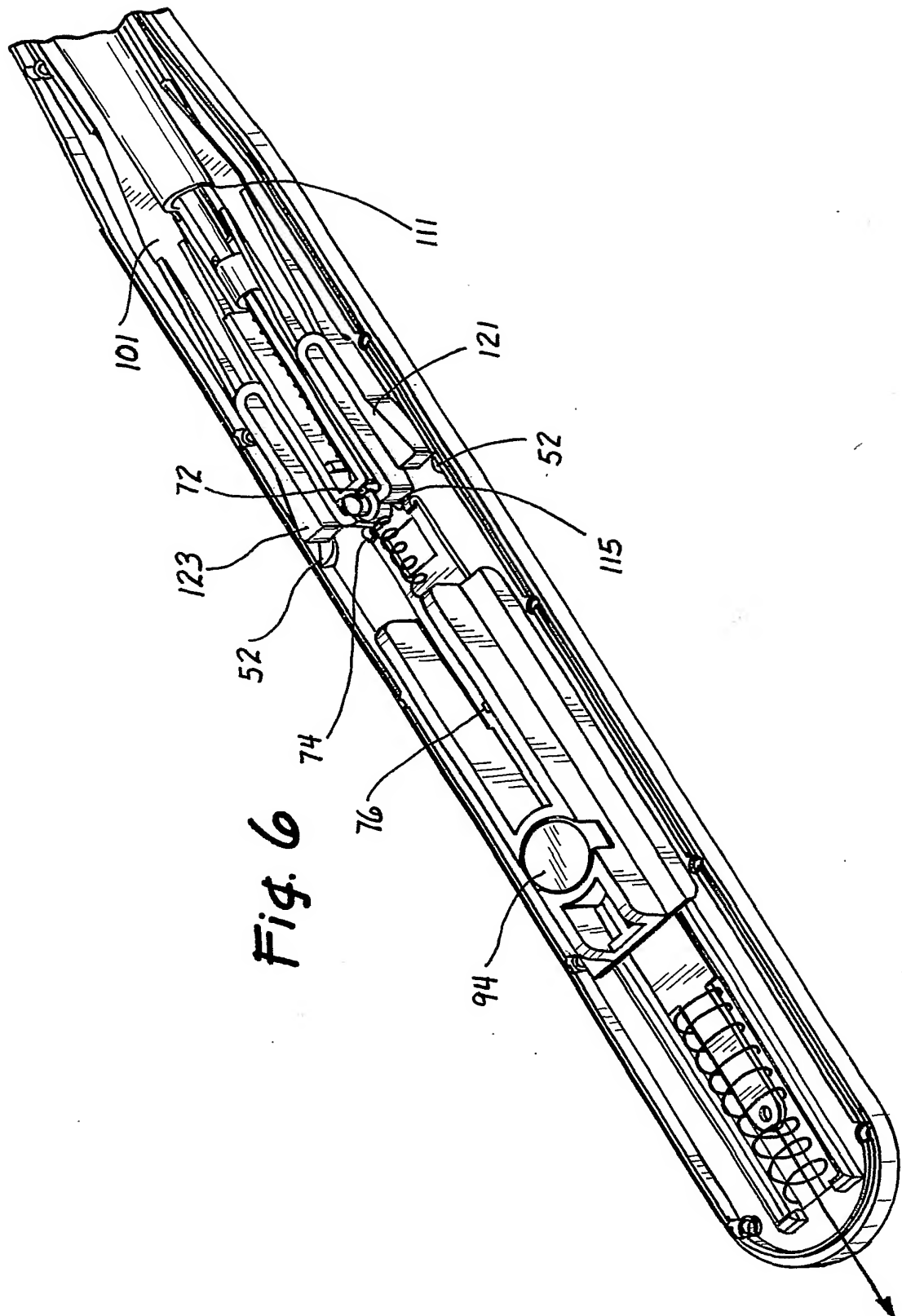
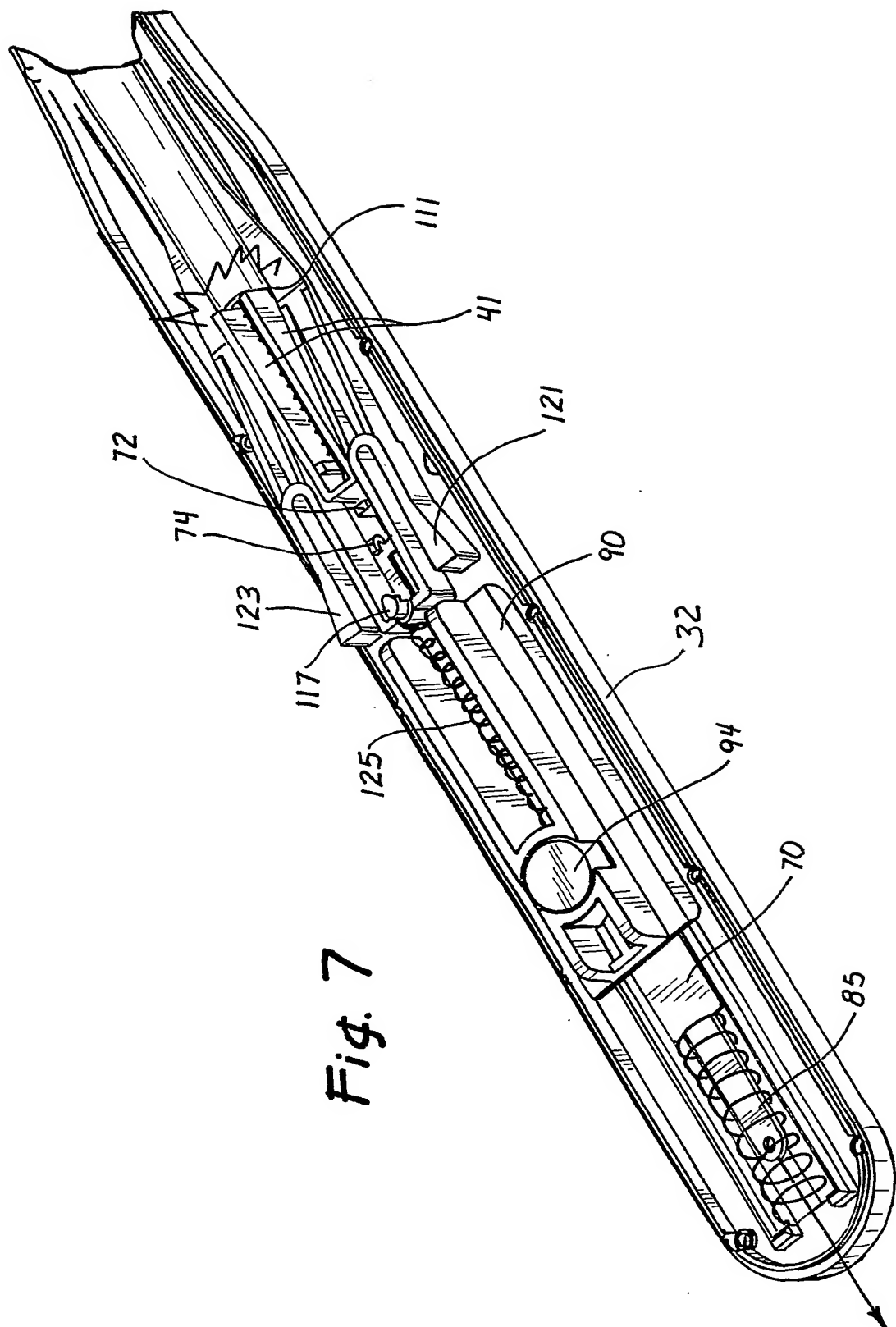


Fig. 5b







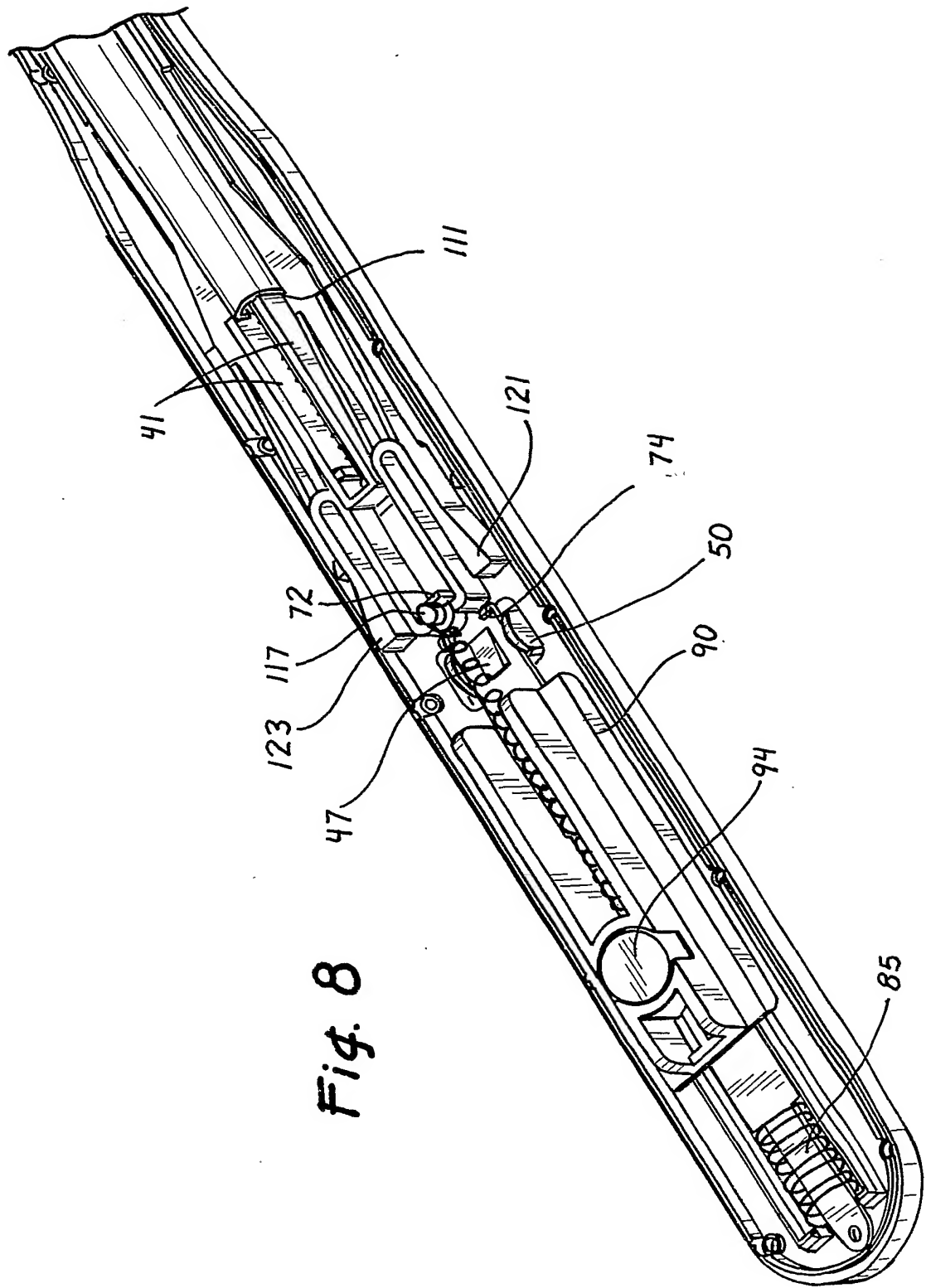
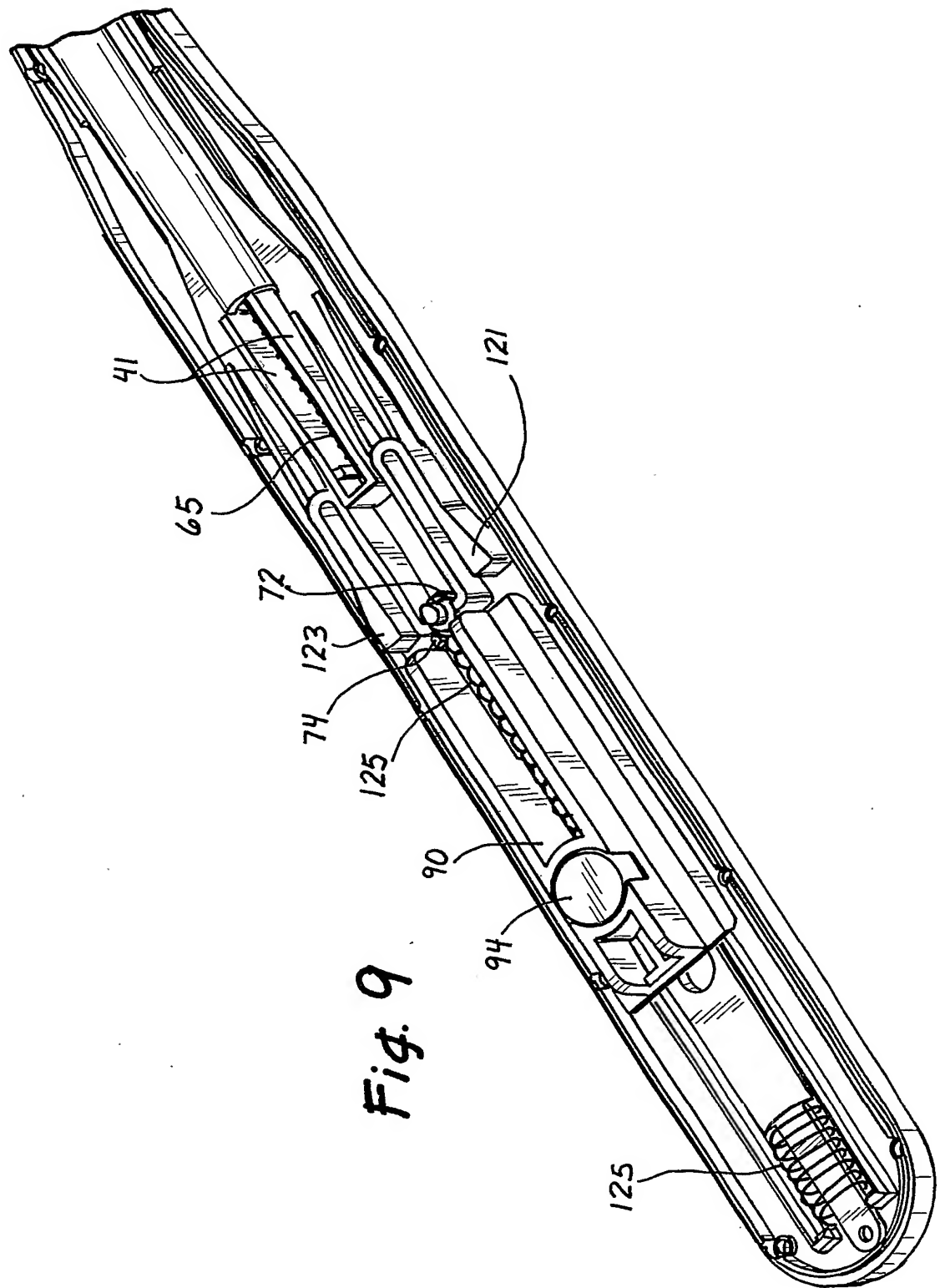


Fig. 8



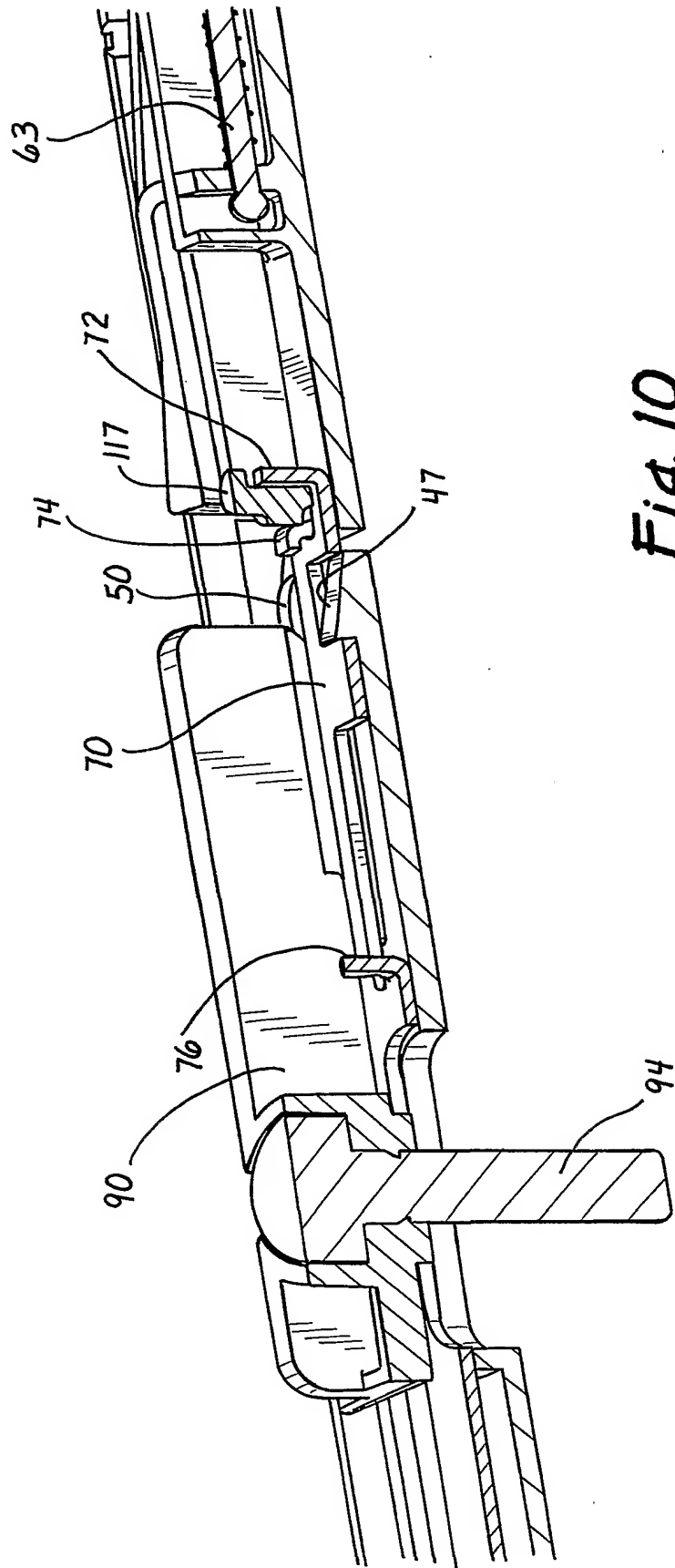
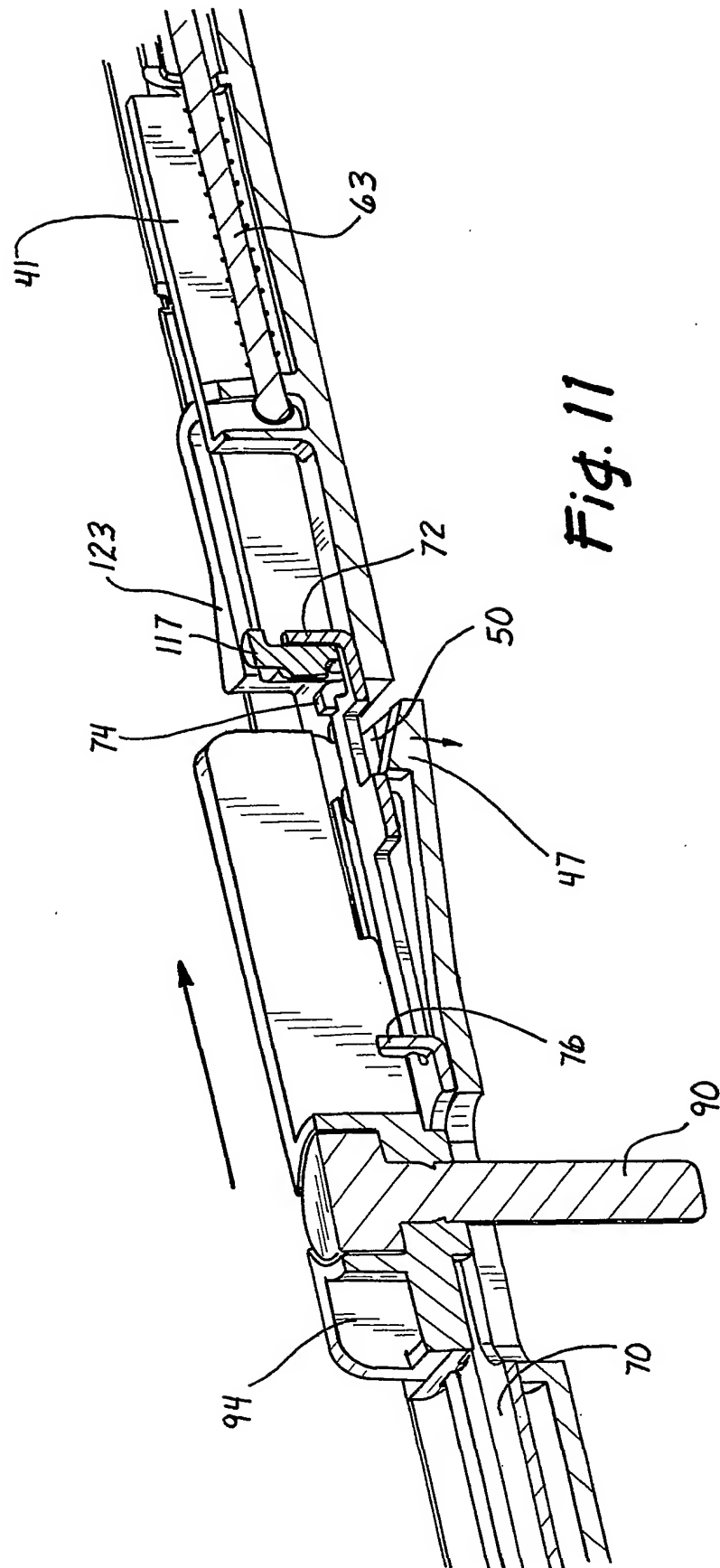


Fig. 10



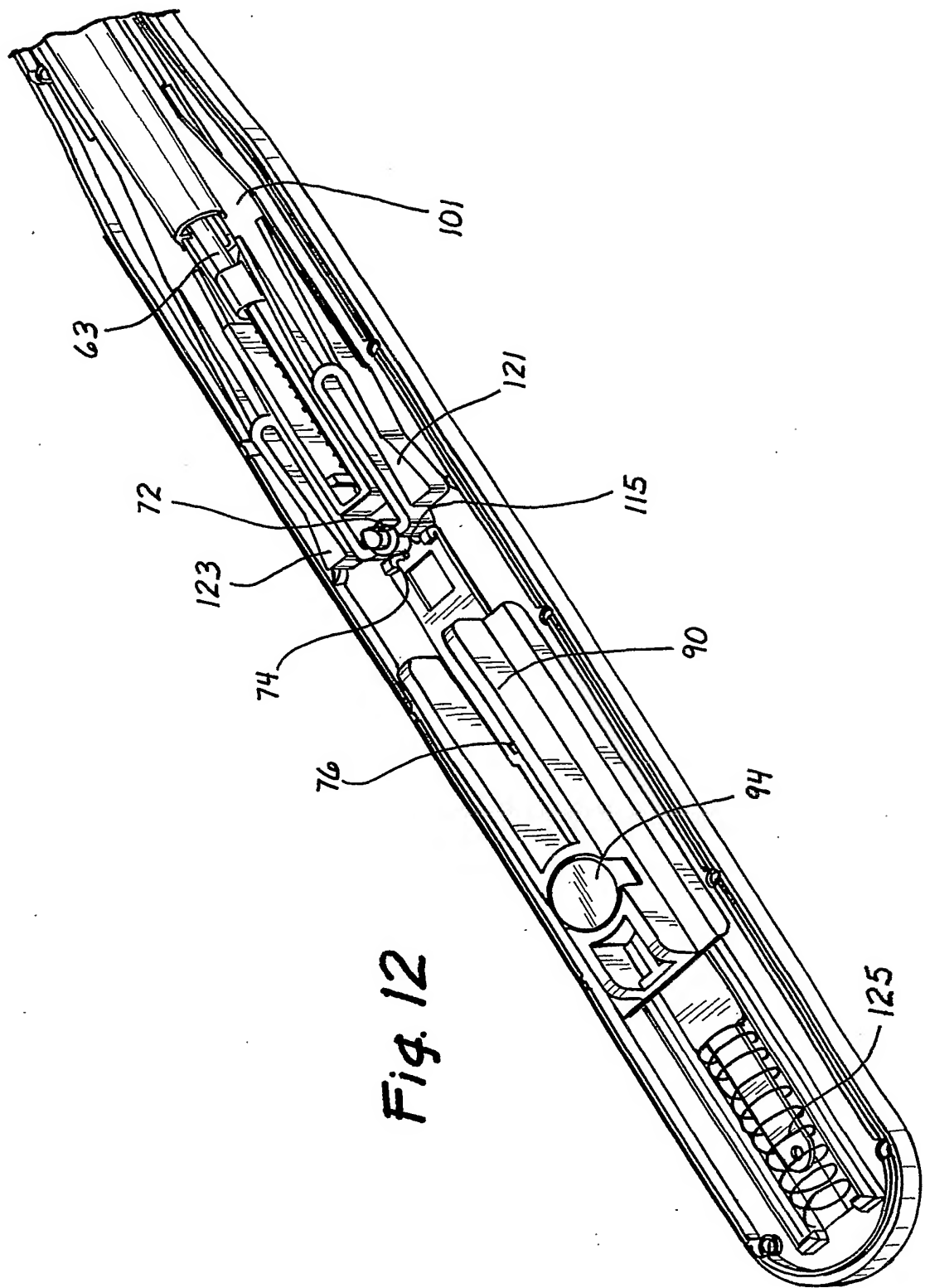


Fig. 12

